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COOPERATIVE EXTENSION
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FDA Docket Clerk
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane Rm. 1061
Rockville, MD 20852

Docket No. 98N-1038

Dear Docket Clerk:

I am a cooperative extension specialist in the Department of Food Science and Technology and the Director of the Center for Consumer Research at the University of California, Davis. My professional training is in consumer attitudes toward food safety and quality. I have conducted research on consumer attitudes toward irradiated products, consulted with others who have investigated this area, studied consumer response to educational programs, and advised on consumer education in the United States and internationally. My comments regarding labeling are based upon my own research, a review of the literature, and over 15 years of interaction with the public on this topic.

Does the current radiation disclosure statement convey meaningful information to consumers in a truthful and nonmisleading manner?

The current radiation disclosure statement does not convey meaningful information to consumers.

Although irradiation has been discussed in the media, many do not understand the technology and are not aware of the purpose or benefits of the treatment. Some consumers are fearful of the word "radiation." (Resurreccion and Galvez, 1999). Virtually every time I speak with consumers about this technology, people volunteer, "You need to come up with a different name. This term is not understood."

Labeling should inform consumers as to the reason a treatment is used or the expected impact of the food. If irradiation treatment is used to destroy

pathogenic bacteria, the more familiar term of pasteurization should be used with a notation that this is accomplished through irradiation. For example, a label might read, "Cold Pasteurized through irradiation to destroy harmful bacteria."

Additionally, multiple strategies should be employed to inform the consumer about the health and safety impact of irradiation treatment. These could include public service announcements, brochures and handouts.

How do consumers perceive the current radiation disclosure statement—as informational, as a warning, or as something else?

Only those consumers who understand the impact of irradiation on food perceive the current statement as informative. Consumers volunteer that this term is scary, therefore it is viewed by many as a warning.

A study with military population indicated that those receiving only a disclosure statement and the radura symbol reported greater concern and were less interested in selecting irradiated food compared to those who received additional information through viewing a video tape prepared at Purdue University. This suggests that the current disclosure statement was viewed negatively. When consumers received additional information, concern decreased and interest in selecting irradiated foods increased (Schutz, 1994). That additional information beyond the disclosure statement reduces concern and increases interest in purchasing irradiated food has been demonstrated in other studies (Pohlman et al, 1994; Bruhn and Mason, 1996).

Does the wording of the current radiation disclosure statement cause "inappropriate anxiety" among consumers? What are examples of "inappropriate anxiety"?

Consumers are not aware of the use of irradiation technology to sterilize personal care and household items and medical equipment. Those not informed about irradiation can be mislead by the current radiation disclosure.

Consumers with lower education and income levels tend to be more concerned about the effects of irradiation (Resurreccion et al, 1995; Lusk, Fox, and McIlvain, 1999). This suggests that the current labeling system may be discriminatory because those with lower education and income are more likely to avoid safety-enhanced irradiated food.

The International Food Information Council (IFIC) focus group research found that some consumers associated the process of irradiation with cancer and x-rays (IFIC, 1998).

Examples of misleading statements that could lead to inappropriate anxiety include pictures of irradiated food that show the product to be an off-color green or glowing. It is not uncommon for the media to indicate that "this food does not glow in the dark," suggesting that consumers might think it does. Promotional material from special interests groups have said, "The government has a solution for the nuclear waste problem, you're going to eat it." The suggestion that irradiated foods use nuclear waste or are radioactive is a gross misrepresentation facilitated by the failure to adequately provide appropriate information for the public.

What specific alternate wording for a radiation disclosure statement would convey meaningful information to consumers, in a truthful and nonmisleading manner, and in a more accurate or less threatening way than the current wording?

Statements should emphasis the reason for the process or the impact of the process on the food.

When irradiation is used to destroy harmful microorganisms, a term which conveys this function should be utilized. For example, the statement could read: "Cold Pasteurized by irradiation to destroy harmful bacteria." Focus group research has indicated that "cold pasteurized" was understood and considered appropriate (IFIC, 1998; Resurreccion and Galvez, 1999).

When irradiation is used for insect dis-infestation, the label could read: "Treated by irradiation for quarantine control," or "Treated by irradiation for safe transport."

When irradiation is used for shelf life extension, the label could read: "Freshness extended through irradiation."

Labeling of spices should be reevaluated. Consumers do not recognize that spices are treated by irradiation or chemical means to meet safety standards. People believe spices are either irradiated or not treated at all. Research indicates that if consumers knew spices were fumigated, they would prefer

irradiated spices (Schutz et al, 1989). FDA should either not require disclosure or mandate full disclosure for all treatments.

Would consumers be misled by the absence of a radiation disclosure statement in the labeling of irradiated foods? Are consumers misled by the presence of such a statement?

Since irradiated foods are evaluated for safety and wholesomeness, consumers do not require information to protect themselves from any risk inherent from irradiated food.

Irradiation treatment is a value added process. When products are irradiated at pasteurization doses, the irradiated product provides added safety and could help protect the consumer from food borne illness. These products should be labeled because of the unique and valuable added protection they provide. When consumers become knowledgeable about the process, most want to select irradiated food (Bruhn, 1995).

Consumers may be misled by the current disclosure requirement which does not emphasize the function of irradiation. Reassurance about safety and expected benefits should be provided.

A label statement must not stand alone. Long-term multi-media consumer education which provides accurate information on this treatment is needed so the public can make an informed decision in the supermarket

Restaurants and food service should be exempt from menu labeling of irradiated food. Labeling of other food processes is not required. The extensive item mixing and daily change of food products in the restaurant would make labeling burdensome. If restaurants chose to label the use of an irradiated item as an indicator of the added safety provided consumers, such labeling should be permitted..

With respect to foods containing irradiated ingredients, are consumers misled by the absence of a radiation disclosure statement? Would consumers be misled by the presence of such a statement?

Since irradiated foods are evaluated for safety and wholesomeness, consumers do not require information to protect themselves from any risk inherent from irradiated food. When irradiated ingredients are present in food, consumers

understand that the food has undergone some form a processing. Irradiation does not change the food's nutritional value or safety in a significant way. FDA should not require labeling of irradiated ingredients.

What is the level of direct consumer experience with irradiated foods that are labeled as such?

When ever given the opportunity, consumers have purchased irradiated food. Purchase rate is higher in up-sale neighborhoods when income and education are higher. Few markets, however, have offered irradiated products and no national poultry processors has offered irradiated poultry. Reluctance appears to relate to restrictive packaging and labeling requirements, limited product approvals (for example processed products such as luncheon meats are not permitted), concern about the image of traditional non-irradiated products, and concern about consumer misunderstanding of irradiation.

Summary of consumer purchases:

PRODUCE: In the mid 1980's a shipment of irradiated mangoes sold well in Florida. A one day market test in Southern California, documented that purchase of labeled irradiated papaya exceeded purchase of non-irradiated by a factor of greater than ten to one (Bruhn and Noel, 1987). Irradiated apples sold well in a market test in the Midwest (Terry and Tabor, 1990). Irradiated produce entered the market on a continuous basis in 1992 (Marcotte, 1992; Pszczola, 1992). The market was expanded to include tropical fruits in 1995. From 1995 to 1999 almost 700,000 pounds of irradiated fruits from Hawaii including papaya, atemoya, rambutan, lychee and starfruit have sold in the Midwest and California (Dietz, 1999).

POULTRY: Consumers in Kansas have purchased labeled irradiated poultry in market tests since 1995. The irradiated poultry captured 63% of the market share when priced 10% less than store brand, and 47 % when priced equally. After reading a brief description of irradiation, 80% selected irradiated poultry when priced the same as the non-irradiated house brand (Fox et al, 1998).

Frozen irradiated poultry is available in independent markets in Polk County, Florida. Endorsement by health officials led to consumer requests for irradiated products (H. Everett, 1999).

What is the effect of the current required labeling on the use of irradiation? Does the current required labeling discourage the use of irradiation?

Because consumers are not informed about irradiation, the current labeling regulations contribute to consumers' concerns that irradiated food may be less safe and nutritious than non-irradiated food.

Current required labeling does not adequately convey necessary information about the benefits of irradiation nor does it include information about the endorsements of this process by the health community. The overall effect is to discourage the purchase of irradiated food, especially among those with lower income and less education.

The food industry is discouraged to use irradiated foods, in part because of the need for consumer education.

What do consumers understand to be the effect of irradiation on food? For example, what do consumers understand about the effect of irradiation on the numbers of harmful microorganisms in or on food?

An increasing number of consumers view irradiation positively because of recent media coverage of the technology. Research in 1998 by the American Meat Institute, Food Marketing Association, Grocery Manufacturers of American and the National Restaurant Association showed that more than 80% of consumers would purchase products labeled, "irradiated to destroy harmful bacteria." People wanted to know about irradiation's effect on the elimination of harmful bacteria and its impact on nutritional value. Destroying disease-causing bacteria was the most important reason for buying irradiated foods, with three-quarters of the respondents saying this was a very important reason for purchase.

The average consumer does not follow these issues closely. Consumers require accurate, informative point of purchase and labeling information so they can make an informed decision at the supermarket.

Do consumers perceive the radura logo as informational, as a warning, or as something else?

Because of limited educational programs and the small amount of irradiated foods on the market, most consumers do not recognize the radura logo. Focus group research (IFIC, 1998) indicated consumers find the image appealing. It is appropriate to include this international symbol when referring to irradiated food. The symbol in itself is not informative. An informative label is needed and an educational program should be launched that explains the effect of irradiation treatment on food safety and quality.

Do consumers understand the logo to mean that a food has been irradiated?

Consumers who have not been informed about irradiation do not understand the intended meaning of the radura logo.

Do consumers perceive the radura logo as informational, as a warning, or as something else?

Consumers do not recognize or understand the radura logo.

Should any requirement for a radiation disclosure statement expire at a specified date in the future?

The radiation disclosure statement should be modified so it is not misleading. Consumers should be informed about the reason for irradiation or the effect of irradiation on the product. Familiar terms should be used. "Cold pasteurized by irradiation to destroy harmful bacteria" meets this criteria.

The question of expiration of a disclosure statement should be revisited after irradiated foods have gained a larger share of the market. Although irradiated foods do not carry any risk, consumers are not familiar with the technology and require additional information.

If so, on what criteria should the expiration be based?

When irradiation is used to enhance the safety of meat and poultry, labeling should be required because consumers need to recognize the value-added product. Milk, for example, is labeled as pasteurized even though this process has been used for many years.

If the expiration of labeling requirements for irradiated foods is to be based on consumer familiarity with the radura logo and understanding of its meaning, what evidence of familiarity and understanding would be sufficient to allow these requirements to expire?

There are always new consumers entering the supermarket. Irradiation as an indicator of enhanced food safety should be required.

I appreciate the opportunity to comment on FDA labeling of irradiated foods. Changes are needed to more fully inform consumers about this technology. Additionally, educational programs on food safety, such as Fight BAC!™ and others, should include information on food irradiation. Educational outreach specifically addressing irradiation should be initiated from credible sources, such as the federal government, health professionals, universities, and food safety professionals.

Food safety is a high priority. Consumers should receive accurate and useful information so they can make informed choices. Irradiation can help protect consumers from foodborne illness. People need to receive this information.

Sincerely

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